REMARKS

This Amendment is submitted in reply to the Non-Final Office Action mailed on March 19, 2009. A petition for a two month extension of time is submitted herewith this Amendment. The Commissioner is hereby authorized to charge $490.00 for the petition for a two month extension of time and any additional fees which may be required or credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 0112701-00697 on the account statement.

Claims 1 and 3-6 are pending in the application. Claim 2 was previously canceled. In the Office Action, Claims 1, 3 and 5-6 are rejected under 35 U.S.C. §112. Claims 1, 3 and 5-6 are also rejected under 35 U.S.C. §102(b). In response, Applicants have amended Claims 1, 3, 5 and 6, and have newly added Claims 7-12. Neither the amendments nor the new claims add new matter. The amendments and newly added claims are supported in the specification at, for example, page 3, lines 8-12; page 5, lines 12-15; page 6, lines 13-18. In view of the amendments and for at least the reasons provided below, Applicants request that the rejections should be withdrawn.

In the Office Action, Claims 5-6 are rejected under 35 U.S.C. §112, first paragraph, because the Patent Office asserts that the specification, while being enabling for treating and/or improving insulin resistance in a certain type of patient having reduced insulin sensitivity, does not reasonably provide enablement for treating and/or improving insulin resistance in any subject to which the instant composition is administered. See, Office Action, page 4, lines 19-23. The Patent Office also states that "[t]he instantly claimed method does not require administration to a patient in need of said treatment of insulin resistance." See, Office Action, page 6, lines 15-17. In response, Applicants have amended Claim 5 to recite, in part, methods for treating and/or improving insulin resistance by reducing insulin resistance which comprises administering to a patient in need of same an effective amount of a composition. The amendment does not add new matter. The amendment is supported in the specification at, for example, page 5, lines 24-30. For at least the above-mentioned reasons, Applicants respectfully submit that Claims 5-6 fully comply with the requirements of 35 U.S.C. §112, first paragraph.

Accordingly, Applicants respectfully request that the rejection of Claims 5-6 under 35 U.S.C. §112, first paragraph, be reconsidered and withdrawn.

In the Office Action, Claims 5-6 are also rejected under 35 U.S.C. §112, second paragraph, because the Patent Office asserts that the "phrase 'effective amount' render the claims indefinite for failing to particularly point out and distinctly claim the subject matter because claims 5 and 6 do not require any limitation on the subject to which said composition is administered." See, Office Action, page 9, line 20–page 10, line 2. The Patent Office also asserts that Claims 5-6 lack the omitted elements of "the patient population to which the administration of said composition is administered to." See, Office Action, page 10, lines 7-12. In response, Applicants reiterate that Claim 5 has been amended to recite, in part, methods for treating and/or improving insulin resistance by reducing insulin resistance which comprises administering to a patient in need of same an effective amount of a composition. Accordingly, because Claim 5 now specifies limitations on the subject to which said composition is administered, Applicants respectfully submit that Claims 5-6 fully comply with the requirements of 35 U.S.C. §112, second paragraph.

In the Office Action, Claims 1, 3 and 5-6 are rejected under 35 U.S.C. §112, second paragraph, because the Patent Office asserts that Claims 1 and 5 recite "improving insulin resistance," which is a relative term that "renders the claim indefinite because it is unclear whether the improvement is to increase insulin resistance, for example an improvement for subject having insulin hypersensitivity, or to decrease insulin resistance." The Patent Office also states that "claim 4 remedies the relative term by specifying increasing insulin sensitivity, implicitly requiring reducing insulin resistance." See, Office Action, page 8, lines 13-16 and 22-23. In response, Applicants note that Claims 1 and 5 have been amended to recite, in part, methods for treating and/or improving insulin resistance by reducing insulin resistance, the methods comprising administering compositions comprising an acetogenic fiber. The amendments do not add new matter. The amendments are supported in the specification at, for example, page 4, lines 15-22; page 5, lines 17-22. As such, Applicants respectfully submit that Claims 1, 3 and 5-6 fully comply with the requirements under 35 U.S.C. §112, second paragraph.

In the Office Action, Claims 3 and 6 are rejected under 35 U.S.C. §112, second paragraph because the claims recite "a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim)." See, Office Action, page 9, lines 1-2. In response, Claims 3 and 6 have been amended to remove the narrow limitations

within each claims. The narrowing limitations within each claim have now been added as newly submitted Claims 7-12. The new claims do not add new matter. The amendments are supported in the specification at, for example, page 3, lines 8-12; page 5, lines 12-15; page 6, lines 13-18. For at least the above-mentioned reasons, Applicants respectfully submit that Claims 1 and 3-6 fully comply with the requirements under 35 U.S.C. §112, second paragraph.

Accordingly, Applicants respectfully request that the rejection of Claims 1 and 3-6 under 35 U.S.C. §112, second paragraph, be reconsidered and withdrawn.

In the Office Action, Claims 1 and 3-6 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Publ. No. 2003/0113390 to Hoie ("*Hoie*"). Claims 1, 3 and 5-6 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,921,877 to Cashmere et al. ("*Cashmere*"). Claims 1 and 3-6 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Publ. No. 2003/0060428 to Hermansen et al. ("*Hermansen*"). In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully submit that *Hoie, Cashmere* and *Hermansen* are deficient with respect to the present claims.

Currently amended independent Claims 1 and 5 recite, in part, methods for treating and/or improving insulin resistance comprising administering to a patient a composition comprising an acetogenic fiber, wherein the acetogenic fibre is lactulose. The amendment does not add new matter. The amendments are supported in the specification at, for example, page 5, line 6. Surprisingly, the present inventors have found that acetogenic fibers have significant effects in improving insulin sensitivity, and in particular, in reestablishing normal insulin sensitivity and thus a normal systemic metabolism. See, specification, page 4, lines 15-17. Without wishing to be bound to any theory it is presently assumed that an increased amount of acetate in blood and tissues – resulting from an administration of a composition according to the present invention results in reduced lipolysis, *i.e.*, a reduced liberation of glycerol and fatty acids from tissues into the blood. This could result in a reduction in the amount of free fatty acids inactivating insulin receptors, which, in turn, could result in an improvement in insulin sensitivity even to the levels present in healthy persons. See, specification, page 5, lines 17-22. In contrast, Applicants submit that the cited references are deficient with respect to the present claims.

For example, *Hoie, Cashmere* and *Hermansen* fail to disclose or suggest methods for treating and/or improving insulin resistance comprising administering to a patient a composition comprising an acetogenic fiber, wherein the acetogenic fibre is lactulose as required, in part, by the present claims. Instead, *Hoie* teaches compositions having soy protein, a phytoestrogen compound and dietary fibers. See, *Hoie*, Abstract. *Cashmere* teaches compositions having a unique fiber-containing carbohydrate blend, a unique fat blend, protein, carnitine, myoinositol, vitamins and minerals for the dietary management of patients with glucose intolerance. See, *Cashmere*, Abstract. *Hermansen* teaches combination drugs having a soy protein and/or a soy fiber and/or at least one isoflavone for the treatment of metabolic syndrome and obesity. See, *Hermansen*, Abstract. At no place in any of the above mentioned references, however, does the disclosure indicate that the compositions contain an acetogenic fiber that is lactulose. Indeed, the Patent Office has not cited any of the above-mentioned references for the disclosure of an acetogenic fiber that is lactulose. Therefore, *Hoie, Cashmere* and *Hermansen* never teach or suggests any compositions comprising an acetogenic fiber, wherein the acetogenic fibre is lactulose as required, in part, by the present claims.

Moreover, anticipation is a factual determination that "requires the presence in a single prior art disclosure of each and every element of a claimed invention." *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987) (emphasis added). Federal Circuit decisions have repeatedly emphasized the notion that anticipation cannot be found where less than all elements of a claimed invention are set forth in a reference. See, *e.g.*, *Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364, 1370 (Fed. Cir. 2002). As such, a reference must clearly disclose each and every limitation of the claimed invention before anticipation may be found. The Patent Office has failed to identify any disclosure in *Hoie, Cashmere* or *Hermansen* that demonstrates that any of the cited references include compositions for treating insulin resistance and having an acetogenic fiber that is lactulose. For at least these reasons, Applicants respectfully submit that the anticipation rejections are improper and that *Hoie, Cashmere* and *Hermansen* fail to anticipate the presently claimed subject matter.

Accordingly, Applicants respectfully request that the anticipation rejections of Claims 1 and 3-6 be reconsidered and withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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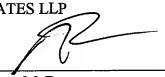
BY 

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